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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/955,680 | 09/19/2001 | Michael J. O'Neil | 101896-0031 | 1266 |
| 21125 | 7590 | 03/22/2005 | EXAMINER | |
| NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 | | | JUNG, WILLIAM C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3737 | |

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/955,680 | O'NEIL, MICHAEL J. | |
| | Examiner | Art Unit | |
| | William Jung | 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 December 2004.
2a) This action is **FINAL**. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-21 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 29012002, 28072003.
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: ____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed December 27, 2004 have been fully considered but they are not persuasive.

In regards to applicant's argument on page 2 with reference to figures 1 and 2 on page 3, the examiner has fully considered the description of the applicant's invention, however, the disclosure nor the claims over come the prior art cited the previous office action. In Perdue's figure 6, the alignment verification device includes spacer element 68 with two elongated members 72 and alignment guide surface 70 with defining orifice where the affixing device such as nail or screw 114 is inserted with engaging element as shown in figure 8. More specifically, the engagement element in figure 8 is threaded screw, i.e., cylinder with slotted element, which is fit to be inserted in spinal disc as prosthesis. Visual indicator as claimed in claims 7 and 19 is disclosed by Perdue in col. 9, lines 14-28. Therefore, Perdue anticipates all claimed features in claims 1, 4, 7, 8, 11, and 17-19.

In regard to claims 3 and 6, Perdue's figure 8 shows that engaging element has finite length defined by the void created by the drilling tool and the depth of the engaging element is limited to the depths.

In regard to claims 16 and 20, claims merely recites that the spacer element can accommodate the prosthesis engaging tool, which is illustrated in figures 6 and 8 where the nail drilled into a patient through the spacer and the same spacer element used to place engaging element 120.

In regard to claim 21, Perdue's figure 8 also shows that the engaging element 120 which previously engaged with the insertion tool is disengaged from the tool.

In regard to inherency, the application of Perdue's invention deals with orthopedic procedure, which includes spinal cord. Although, Perdue do not explicitly state that his device is used for spinal surgery, it is a part or subset of orthopedic surgery.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by *Perdue* (US 4,848,327).

Claims 1, 4, 7-11, 16, 17, and 19-21: Perdue discloses a method and apparatus where an alignment device aligns a verification or guidance device such as x-ray image device. Perdue further discloses that the device described above includes an elongated spacer element 10 having proximal and distal portions and an insert engaging element disposed on the distal portion and an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the insert engaging element. In addition, Perdue discloses that the device described above where the aligning of the x-ray device is used to insert prosthesis during orthopedic surgery. Moreover, the alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the prosthesis engaging element and a prosthesis having an engaging element and a visual

indicator element, the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced-apart from the visual indicator element (col. 7, line 46 – col. 8, line 51; col. 9, line 14 – col. 11, line 36).

Claims 2, 3, 5, 6, 12-15 and 6: Perdue's disclosure of alignment device is used in orthopedic procedure. The spinal disc surgery is considered orthopedic procedure therefore, Perdue inherently anticipate the use of the alignment device in spinal disc prosthesis.

Claim 18: Perdue also discloses optical visual marker, although not explicitly stated as laser marker, to create sight line for the insertion element, which may include laser pointer (col. 11, lines 19-36).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

wcj
March 21, 2005

Brian L. Casler
BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700